

Union Calendar No. 90

104TH CONGRESS  
1ST SESSION

**H. R. 587**

[Report No. 104-178]

**A BILL**

To amend title 35, United States Code, with respect to patents on biotechnological processes.

JULY 11, 1995

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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### IN THE HOUSE OF REPRESENTATIVES

JANUARY 19, 1995

Mr. MOORHEAD (for himself, Mr. BOUCHER, Mr. SENSENBRENNER, Mr. COBLE, Mr. FRANK of Massachusetts, Mr. GALLEGLY, Mr. GOODLATTE, Mr. GEKAS, Mr. BONO, Mr. CANADY of Florida, and Mr. HOKE) introduced the following bill; which was referred to the Committee on the Judiciary

JULY 11, 1995

Additional sponsors: Mr. BERMAN, Ms. DANNER, Mr. ROHRABACHER, Mr. EVANS, Mr. BRYANT of Texas, Mr. KLUG, Mr. McHALE, Mr. FOX of Pennsylvania, Mr. ROYCE, Mr. FORBES, Mrs. MEYERS of Kansas, Ms. ESHOO, Mr. BLUTE, Mr. SAXTON, Mr. ZIMMER, Mr. FATTAH, Mr. CONYERS, and Mr. REED

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## A BILL

To amend title 35, United States Code, with respect to  
patents on biotechnological processes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3               BIOTECHNOLOGICAL PROCESS PATENTS

4       **SEC. 101. CONDITIONS FOR PATENTABILITY; NONOBVIOUS**  
5               **SUBJECT MATTER.**

6       Section 103 of title 35, United States Code, is  
7       amended—

8               (1) by designating the first paragraph as sub-  
9       section (a);

10              (2) by designating the second paragraph as  
11       subsection (c); and

12              (3) by inserting after the first paragraph the  
13       following:

14       “(b)(1) Notwithstanding subsection (a), and upon  
15       timely election by the applicant for patent to proceed  
16       under this subsection, a ‘biotechnological process’ using or  
17       resulting in a composition of matter that is novel under  
18       section 102 and nonobvious under subsection (a) of this  
19       section shall be considered nonobvious if—

20              “(A) claims to the process and the composition  
21       of matter are contained in either the same applica-  
22       tion for patent or in separate applications having the  
23       same effective filing date; and

24              “(B) the composition of matter, and the process  
25       at the time it was invented, were owned by the same

1 person or subject to an obligation of assignment to  
2 the same person.

3 “(2) A patent issued on a process under paragraph  
4 (1)—

5 “(A) shall also contain the claims to the com-  
6 position of matter used in or made by that process,  
7 or

8 “(B) shall, if such composition of matter is  
9 claimed in another patent, be set to expire on the  
10 same date as such other patent, notwithstanding  
11 section 154.

12 “(3) For purposes of paragraph (1), the term  
13 ‘biotechnological process’ means—

14 “(A) a process of genetically altering or other-  
15 wise inducing a single- or multi-celled organism to—

16 “(i) express an exogenous nucleotide se-  
17 quence,

18 “(ii) inhibit, eliminate, augment, or alter  
19 expression of an endogenous nucleotide se-  
20 quence, or

21 “(iii) express a specific physiological char-  
22 acteristic not naturally associated with said or-  
23 ganism;

1           “(B) cell fusion procedures yielding a cell line  
2           that expresses a specific protein, such as a  
3           monoclonal antibody; and

4           “(C) a method of using a product produced by  
5           a process defined by (A) or (B), or a combination  
6           of (A) and (B).”.

7   **SEC. 102. PRESUMPTION OF VALIDITY; DEFENSES.**

8           Section 282 of title 35, United States Code, is  
9   amended by inserting after the second sentence of the first  
10 paragraph the following: “Notwithstanding the preceding  
11 sentence, if a claim to a composition of matter is held in-  
12 valid and that claim was the basis of a determination of  
13 nonobviousness under section 103(b)(1), the process shall  
14 no longer be considered nonobvious solely on the basis of  
15 section 103(b)(1).”.

16   **SEC. 103. EFFECTIVE DATE.**

17           The amendments made by section 101 shall apply to  
18 any application for patent filed on or after the date of  
19 enactment of this Act and to any application for patent  
20 pending on such date of enactment, including (in either  
21 case) an application for the reissuance of a patent.